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HEADLINE: Congressional Panel to Study Off-Label Use of Stents, Drugs

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BODY:

A congressional committee is looking into the "off label" use of drugs and heart stents, examining the widespread practice in which doctors prescribe medical products to patients outside the boundaries approved by the Food and Drug Administration.

Boston Scientific Corp. and Johnson & Johnson's Cordis unit, the only makers of drug-coated stents sold in the U.S., were asked to submit marketing materials and clinical data to the House Committee on Oversight and Government Reform on Wednesday. About 60% of drug-coated stents, which prop open clogged arteries, are used off-label. For example, manufacturers haven't rigorously tested their stents in patients who have had heart attacks, but stents are commonly given to such patients. Doctors are allowed to prescribe stents to off-label patients, but manufacturers can't encourage off-label use.

The committee's chairman, California Democrat Henry Waxman, also asked for marketing materials from three drug companies that have come under scrutiny over whether they promoted their products for unapproved uses: Eli Lilly & Co., whose antipsychotic drug Zyprexa had \$4.36 billion in sales last year and was the company's best seller; AstraZeneca PLC, which makes another depression drug, Seroquel; and Cephalon Inc., whose marketing of painkillers has been under investigation by the Connecticut attorney general.

A spokeswoman for Mr. Waxman said the committee hadn't initiated a formal investigation and characterized the letters as a preliminary look at off-label use, "given the allegations that have been out there." Last month, the agency that runs Medicare said it also was examining off-label uses of drug-coated stents.

Boston Scientific, Johnson & Johnson and Lilly said they will cooperate with the committee's inquiry. AstraZeneca and Cephalon couldn't be reached for comment yesterday evening.

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